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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,922	06/13/2001	Karin Angela Hing	HING3001/REF	8656

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EXAMINER

FIORILLA, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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1731

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,922

Applicant(s)

HING ET AL.

Examiner

Christopher A. Fiorilla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1,4-27,32,33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897) for the reasons as set forth in the previous office action.

4. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897) as applied to claims 1,4-27,32,33 and 35-39 above, and further in view of Wu (5,656,562) for the reasons as set forth in the previous office action.

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5. Claims 2,3 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897) as applied to claims 1,4-27,32,33 and 35-39 above, and further in view of Nukada et al. (5,395,722).

Nukada et al. discloses the use of alumina and zirconia media of 1-30mm size for use in a ball mill (col. 5, lines 60-65). It would have been obvious to one skilled in the art at the time of the invention to use this type of media in the process of WO 93/04013 in view of the generic disclosure therein.

6. Applicants' arguments filed 1/13/03 have been fully considered but are not persuasive.

With respect to the rejection under 35 USC 103 applicants argue:

Claim 1 is novel over WO 93/04013 for at least the reason that this prior art document does not disclose the step of foaming a ceramic slip using a ball mill.

This argument is not persuasive. The examiner admits that claim 1 is novel over WO 93/04013. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is clear that WO 93/04013 achieves foaming by the injection of gas into the dispersion.

This argument is not persuasive. It is submitted that this is a mischaracterization of the reference. WO 93/04013 is not limited to foaming by this method. Page 5, line 4, refers to gas entrapment by mechanical means rather than injection of gas into the dispersion.

Claim 1 is further distinguished from WO 93/04013 in that the claimed method is directed to a method of producing a macroporous ceramic foam for use in biomedical

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applications and having an open foam structure containing pores with a modal diameter greater than or equal to 100 microns.

This argument is not persuasive. The examiner admits that claim 1 is novel over WO 93/04013. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Note however that page 10, second paragraph of WO 93/04013 discloses the materials are suitable for artificial parts of the body (i.e. biomedical applications).

Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of WO 93/04013 based on the teaching of US 5,895,897. In particular there is no suggestion in either WO 93/04013 or US 5,895,897 that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of WO 93/04013 and US 5,895,897.

This argument is not persuasive. First, it is submitted there need not be a suggestion that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. WO 93/04013 teaches the foaming of a ceramic slip or slurry but does not require a specific method of foaming the slip. In fact, page 5, line 4, generically refers to "mechanic means". Thus, one of ordinary skill in the art would look to references which teach mechanic means of foaming in order to carry out the invention. Oishi et al. US 5,895,897, teaches that foaming may be carried out by ball milling. Thus, there is indeed motivation to combine the teachings of WO 93/04013 and US 5,895,897.

It is further noted that the method according to WO 93/04013 does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material as contemplated by the present application. For this purpose, the foamed

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macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size greater than or equal to 100 microns. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording in claim 1. Indeed, the reference to the Buchner funnel in examples 2,3 and 4 of WO 93/04013 would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 microns.

This argument is not persuasive. First, it is submitted again that page 10 of WO 93/04013 discloses that the porous articles formed by the process therein are suitable for artificial parts for the body (lines 10-11). Note also that WO 93/04013 teaches that the porosity may be open porosity (page 11, line 7). Although WO 93/04013 discloses some examples of pore sizes, it does not disclose a specific pore size formed by a mechanical method. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Note however that page 10, second paragraph of WO 93/04013 discloses the materials are suitable for artificial parts of the body (i.e. biomedical applications). Finally, note that arguments of counsel cannot take place of evidence in the record. *In re Pearson*, 494 F.2d 1399, 1405, 181 USPQ 641,646 (CCPA 1974).

Document US 5,895,897 does not disclose a method of producing synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to US 5,895,897 as an open microporous structure with a modal pore size greater than or equal to 100 microns, as required by claim 1 of the present application.

This argument is not persuasive. First, US 5,895,897 was not cited by the examiner to teach biomedical applications. Further, note that col. 8, line 21 recites that the voids are continuous (i.e. open porosity). US 5,895,897 also discloses pore sizes up to 5000 microns. This would encompass modal pore sizes greater than or equal to 100 microns. In the case where the

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claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

US 5,656,562 merely describes the conventional technique of using grinding media to mill starting powders. US 5,656,562 is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications. In view of the above comments, it is considered that the disclosure of US 5,656,562 has been taken out of context and the Examiner's rejection should most respectfully be withdrawn.

This argument is not persuasive. US 5,656,562 is cited to teach a conventional size of grinding media. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller* 208 USPQ 871, 881; *In re Sernaker* 217 USPQ 1.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Fiorilla whose telephone number is 703-308-0674. The examiner can normally be reached on M-F, 6:30am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on 703-308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

A handwritten signature in black ink, appearing to read 'ca Fiorilla', with a stylized flourish at the end.

Christopher A. Fiorilla
Primary Examiner
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